K082488

## 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

| | |
|---|---|
| **Submitter's name:** | Diazyme Laboratories |
| **Submitter's address:** | 12889 Gregg Court<br>Poway, CA 92064<br>USA |
| **Name of Contact Person:** | Dr. Abhijit Datta<br>Diazyme Laboratories<br>12889 Gregg Court<br>Poway, CA 92064<br>Phone: 858-455-4762<br>Fax: 858-455-2120 |
| **Date the Summary was Prepared:** | Aug 26, 2008; Dec 1, 2008 |
| **Name of the Device** | Diazyme Lipoprotein (a) Assay |
| **Trade Name:** | Diazyme Lp(a) Assay |
| **Common/Usual Name** | Lp(a) Test System |
| **Device Classification Name** | Low Density Lipoprotein Immunological Test System |
| **Product code:** | DFC, JIS, JJX |
| **Submission Type** | 510k |
| **Regulation Number** | 866.5600, 862.1150, 862.1660 |
| **Device Class** | II |
| **Predicate Device:** | For the Lipoprotein (a) Immunological Test System Lipoprotein test system, we are claiming equivalence to Lp(a)-LATEX SEIKEN ASSAY KIT manufactured by Denka Seiken Co. Ltd |

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## Substantial Equivalence Information

1. **Predicate device name(s):**

   Lp(a) Assay

2. **Predicate 510(k) number(s):**

   K013359

3. **Comparison with predicate:**

**Indications for Use**

| Diazyme Lp(a) Assay | Denka Lp(a) Assay | Equivalency |
|---|---|---|
| The Diazyme Lp(a) immunoassay is intended for the *in vitro* quantitative determination of Lipoprotein (a) in human serum and plasma. | The Lp(a) Assay is a latex in vitro diagnostic immunoassay for the quantitative determination of Lipoprotein (a) in human serum and plasma. | Same |

**Principle**

| Diazyme Lp(a) Assay | Denka Lp(a) Assay | Equivalency |
|---|---|---|
| The Diazyme Lipoprotein (a) Assay is based on a latex enhanced immunoturbidimetric assay. Lp(a) in the sample binds to specific anti-Lp(a) antibody, which is coated on latex particles, and causes agglutination. The degree of the turbidity caused by agglutination can be measured optically and is proportional to the amount of Lp(a) in the sample. | The Lp(a)-Latex Seiken Assay kit is a latex-enhanced immunoturbidimetric *in vitro* diagnostic assay. Lp(a) in the sample binds to the specific anti-Lp(a) antibody, which is adsorbed to latex particles and agglutinates. The agglutination is detected as an absorbance change when read on an automated chemistry analyzer (at 700 nm). The magnitude of the change is proportional to the quantity of Lp(a) in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of know concentrations. | Same |

**Test Objective**

| Diazyme Lp(a) Assay | Denka Lp(a) Assay | Equivalency |
|---|---|---|
| For the *in vitro* quantitative determination of lipoprotein (a) in serum or plasma. | For the *in vitro* quantitative determination of lipoprotein (a) in serum or plasma using automated chemistry analyzers. | Same |

**Type of Test**

| Diazyme Lp(a) Assay | Denka Lp(a) Assay | Equivalency |
|---|---|---|
| Quantitative | Quantitative | Same |

**Specimen Type**

| Diazyme Lp(a) Assay | Denka Lp(a) Assay | Equivalency |
|---|---|---|
| Human serum and plasma | Human serum and plasma | Same |

**Product Type**

| Diazyme Lp(a) Assay | Denka Lp(a) Assay | Equivalency |
|---|---|---|
| Calibrator, Reagent, Instrument | Calibrator, Reagent, Instrument | Same |

**Performance**

| Diazyme Lp(a) Assay | Denka Lp(a) Assay |
|---|---|
| Reportable Range:<br>Serum: **5.44 mg/dL to 100.0 mg/dL**<br>Plasma: **5.44 mg/dL to 100.0 mg/dL**<br>Precision/Serum:<br>Within Run: **1.1% - 2.6%**<br>Total: **2.4% - 3.6%**<br>Accuracy/Serum:<br>Correlation Coefficient: **0.998**<br>Slope/Intercept:<br>**y = 0.9895x + 0.0279**<br>Accuracy/Plasma:<br>Correlation Coefficient: **0.9803**<br>Slope/Intercept:<br>**y = 1.044x + 0.0407** | Reportable Range:<br>Serum: **0.5mg/dL to 80.0 mg/dL**<br>Plasma: **0.5mg/dL to 80.0 mg/dL**<br>Precision/Serum:<br>Within Run: **1.26% - 2.00%**<br>Total: **0.99% - 2.22%**<br>Accuracy/Serum:<br>Correlation Coefficient: **0.989**<br>Slope/Intercept:<br>**y = 1.108x – 1.44**<br>Accuracy/Plasma:<br>Correlation Coefficient: **0.990**<br>Slope/Intercept:<br>**y = 1.079x – 0.16** |

**Calibrator Comparison**

| Diazyme Lp(a) Assay | Denka Lp(a) Assay | Equivalency |
|---|---|---|
| Lyophilized form | Lyophilized form | Same |

**Control Comparison**

| Diazyme Lp(a) Assay | Denka Lp(a) Assay | Equivalency |
|---|---|---|
| Lyophilized form | Lyophilized form | Same |

**Rationale for Considering the Device Substantially Equivalent to Devices Approved for Interstate Commerce**

The Denka Lp(a) Assay (k013359) was selected for method comparison testing of human serum and plasma samples with the Diazyme Lp(a) Assay. Detailed performance characteristics and comparison analysis are given in this filing and demonstrate substantial equivalence to predicate device that is currently being legally marketed.

The Diazyme Lp(a) Assay is substantially similar to the approved predicate test. The minor differences in the performances of the tests should not affect the safety and effectiveness of the Diazyme Lp(a) Assay and offers users an *in-vitro diagnostic* device to measure Lp(a) in human serum and plasma.

**Description of the Device**

Lipoprotein (a) is a cholesterol-rich lipoprotein particle found in human serum. There is substantial evidence linking lipoprotein (a) excess to a high risk for premature coronary heart disease (CHD), increased risk of myocardial infraction (MI) and stroke, and restenosis after angioplasty (PTCA) and coronary bypass procedures. Lipoprotein (a) has been called a powerful predictor of premature atherosclerotic vascular disease. Therefore measurement of lipoprotein(a) is now recommended in several patient subgroups for whom excess lipoprotein(a) may have important clinical consequences: (1) patients with premature athero-sclerosis, (2) patients with a strong family history of premature coronary heart disease (CHD), (3) patients with elevated LDL-C and greater than or equal to two risk factors, (4) patients who have had coronary angioplasty in whom lipoprotein(a) excess may increase the risk of restenosis, and (5) patients who have undergone coronary bypass graft surgery in whom Lp(a) excess may be associated with graft stenosis.

**Intended Use of the Device:**
The Diazyme Lipoprotein (a) [Lp(a)] Assay and Lipoprotein (a) Assay Calibrator Set are intended for the in vitro quantitative determination of lipoprotein (a) in serum or plasma.

**Performance Testing Summaries**

Precision

The Diazyme Lipoprotein (a) Assay is based on a latex enhanced immunoturbidimetric assay. Lp(a) in the sample binds to specific anti-Lp(a) antibody, which is coated on latex particles, and causes agglutination. The degree of the turbidity caused by agglutination can be measured optically and is proportional to the amount of Lp(a) in the sample.

The precision of the Diazyme Lp(a) Enzymatic Assay was evaluated according to Clinical and Laboratory Standards Institute (formerly NCCLS) EP5-A guideline. In the study, three levels of serum specimens containing about 17.2, 43.2, and 70.0 mg/dL Lp(a) respectively are tested with 2 runs per day with duplicates over 20 working days.

| Serum Testing | **Level 1** | **Level 2** | **Level 3** |
|---|---|---|---|
| Within-Run Precision | $C_V\% = 2.6\%$ | $C_V\% = 1.4\%$ | $C_V\% = 1.1\%$ |
| Total Precision | $C_V\% = 3.6\%$ | $C_V\% = 3.3\%$ | $C_V\% = 2.4\%$ |

Accuracy

Correlation studies were performed by testing 76 serum samples in comparison with an existing commercial Lp(a) assay method. The result summary indicates good agreement with legally marketed assay.

Accuracy Summary:

Serum:
Correlation Coefficient: 0.9983
Slope/Intercept:

$y = 0.9891x + 0.0947$

Plasma:
Correlation Coefficient: 0.9803
Slope/Intercept:
$y = 0.9895/0.0279$

Interference

We have conducted interference studies by spiking human serum samples with substances normally present in serum and found less than 10% interference at the indicated concentrations.

| **Interference Study** | |
|---|---|
| **Substance** | **Concentration** |
| Triglycerides | 1000 mg/dL |
| Ascorbic acid | 10 mmol/L |
| Bilirubin | 40 mg/dL |
| Bilirubin Conjugated | 40 mg/dL |
| Hemoglobin | 1000 mg/dL |

**Conclusion:** Detailed comparison analysis presented in this 510k submission, together with linearity, precision and interference and other detailed studies, demonstrates that the Diazyme Lp(a) Assay has excellent accuracy and is safe and effective. There is no significant deviation between the results obtained by Diazyme Lp(a) Assay and the legally marketed predicate device (k013359) when testing clinical patient samples and is therefore substantially similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

General Atomics
Diazyme Laboratories
c/o Dr. Abhijit Datta
12889 Gregg Court
Poway, CA 92064

JAN 13 2009

Re: k082488
Trade/Device Name: Diazyme LP(a) assay
Regulation Number: 21 CFR 866.5600
Regulation Name: Low-Density Lipoprotein Immunological Test System.
Regulatory Class: Class II
Product Code: DFC, JIT, JJX
Dated: December 1, 2008
Received: December 4, 2008

Dear Dr. Datta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

# Indication for Use

510(k) Number (if known): k082488

Device Name: Diazyme Lp(a) Assay

Indication For Use:

The Diazyme Lp(a) is intended as a latex particle enhanced immunoturbidimetric assay for the in vitro quantitative determination of lipoprotein(a) [Lp(a)] concentration in human serum or plasma (EDTA) on Clinical Chemistry Systems. The measurement of Lp(a) is useful in evaluating lipid metabolism disorders and assessing atherosclerotic cardiovascular diseases in specific populations, when used in conjunction with clinical evaluation.

Diazyme Lp(a) Control is intended for use in monitoring the quality control of results obtained with the Diazyme Lp(a) reagents by turbidimetry.

Diazyme Lp(a) standard is intended for use in establishing the calibration curve for the Diazyme Lp(a) reagents by turbidimetry.

Prescription Use __X__ And/Or Over the Counter Use ___.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K082488